

REMARKS

The applicants and the undersigned thank the Examiner for the courtesy of the Examiner's Interview which took place on August 3, 2006. This amendment makes the comments which took place at the Interview of record in the case.

Spelling, grammatical and textual errors in the specification have been corrected. No new matter has been added.

Claims 1 and 35-39 have been canceled without prejudice or disclaimer. At the interview, the Examiner noted that the subject matter of claims 1 and 35-39 was different from that set forth in claims 2 and 4-27, and that a restriction requirement would likely be required in the case. Therefore, to speed up prosecution of the case, claims 1 and 35-39 have been canceled, The application now includes claims 2 and 4-27

Cancellation of claims 1 and 35-39 makes moot the rejection for obviousness based on U.S. Patent 6,381,577 to Brown in view of U.S. Patent 6,108,635 to Herren.

Claims 2, 14, 15, 26, and 27 were rejected as being obvious over Herren in view of Brown. Claims 4-13 and 16-25 were rejected as being obvious over Herren and Brown in view of U.S. Patent 6,861,003 to Linder. Both rejections are traversed.

As was agreed at the interview, none of Herren, Brown, or Linder disclose or suggest

- receiving a user's profile at a server, and matching the user's profile to one or more clinical trials in which he or she may participate;
- providing a clinical trial module to a client when the client elects to participate in the trial, where the clinical trial module permits clinical trial data including data observations for the trial to be obtained from the client;
- receiving data observations at the server and storing them; or
- producing reports based on a plurality of observations which are obtained during the conduct of the clinical trial.

In view of this, none of claims 2 and 4-27 would be obvious over any combination of the references of record.

As discussed at the Interview, Claim 2 of the present application is drawn

to a method which permits clients (e.g., individual patients) to provide their individual profile to a server which then determines whether the client's profile would match current or planned clinical trials in which, for example, he or she might be enrolled. When the server receives a clinical trial selection from the client (e.g., the client indicates he or she wants to participate), a selected clinical trial module is provided to the client. Then, data observations are obtained from the client that are pertinent to the trial and stored in a database. Reports are made in response to report requests which include a plurality of retrieved observations. Thus, the claimed invention permits a person to identify trials in which he or she may participate, and once entered into the trial, to provide data for the trial, and to allow the data to be prepared into reports.

In sharp contrast to the invention, Herren describes data mining. The passage in column 10 referenced by the Examiner, discusses comparing proposed interventions in patients with different attributes and risk factors under different intervention regimens. Thus, in Herren, nobody is being enrolled in anything (i.e., the data is already collected and is now being mined). As such, Herren does not show or suggest receiving a user's profile and matching the user to a particular clinical trial.

The Herren reference purportedly describes an integrated disease information system. As discussed in the Abstract, the Herren system allows a researcher to engage in sophisticated data mining in order to analyze disease progression and interventions in various patient populations. As shown in the drawings of Herren, Herren does not contemplate a system where information is gathered from a specific measurement device for a specific patient. Rather, Herren is related to analyzing biological, patient and population data that has already been collected and stored.

Brown does not make up for this deficiency in Herren. The Brown reference purportedly describes a multi-user health monitoring system. Figure 2 shows measurements can be taken at a remote apparatus and be provided to a server. Examples include glucose measurements, blood pressure etc. Furthermore, Brown describes posing questions to a patient and receiving input on various symptoms (see Figure 8). Figure 9 of Brown shows cursory instructions on performing a test and having the results sent to the server. Figure 19 shows

communicating appointment information to a patient. Figure 20 shows communicating a lab report to a patient. Apparatus 26 is common to each of these figures, and it can be seen from Figure 2 that apparatus 26 is separate from monitoring device 28. As noted in column 6, line 13-14 and 62, apparatus 26 is designed to be used by a plurality of patients and may be located, for example, at a pharmacy counter. Column 7 of Brown, at lines 8 et seq., discusses connecting the apparatus 26 to any of a variety of monitoring devices. As such, in operation, data from a monitoring device is either stored in the monitoring device until it is connected with apparatus 26, or the patient connects the device 28 at the pharmacy and performs the test on the spot.

In short, Brown is unrelated to clinical trials and makes no reference whatsoever to enrollment or a person in one or more clinical trials. Brown relates to collecting information. Herren relates to analyzing information. Any combination of the two would not suggest or make obvious to one of ordinary skill in the art a method or system which allows patients to easily enroll in and participate in clinical trials by providing their profiles, selecting from a matched clinical trial, and providing observations to be used in the clinical trial

Claim 14, similar to claim 1, requires receiving a user profile, matching a clinical trial based on the profile, and providing modules for collecting data. Similarly, claim 26, which is drawn to a clinical trial client, requires providing the profile and receiving the matching trial information. As such, none of claims 2, 14, 15, 26, and 27 would be obvious over any combination of Herren and Brown.

Furthermore, Linder does not make up for the deficiencies of a combination of Herren and Brown. That is Linder does not suggest providing a patient profile to a server or matching that profile to a clinical trial. A search of the Linder reference will reveal that at no point does Linder mention a clinical trial. The Linder reference purportedly describes a data collection and management system where information is retrieved from an implantable or patient worn device. The data which is collected can be used to monitor either health related aspects of the patient, or the performance of the device itself. Updates are transmitted to the patient device when collected data is downloaded.. Furthermore, Linder is focused on a single observation. For example, how has the patient's heart responded to stimulation? Or, has the electrical stimulation been provided in a

timely fashion over the last week?


Herren and Brown are directed to diverse subject matter and would not be combined as suggested. The only commonality between the two is that they pertain to computer systems which are employed in healthcare. However, Herren is focused on data mining, analysis of interventions, and analysis of observations during clinical trials, while Brown is focused on collecting data from a plurality of specific patients in a convenient manner from remote locations (e.g., pharmacies). In addition, Linder is focused on a particular patient, and thus would not be properly combinable with Herren which is focused on mining information from a plurality of patients.

In view of the foregoing, it is respectfully requested that the application be reconsidered, that claims 2 and 4-27 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or personal interview.

A provisional petition is hereby made for any extension of time necessary for the continued pendency during the life of this application. Please charge any fees for such provisional petition and any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



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